**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| ENDO PHARMACEUTICALS INC. and PENWEST PHARMACEUTICALS CO., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C. A. No. _____ |
| IMPAX LABORATORIES, INC., | ) | |
| Defendant. | ) | |

**COMPLAINT**

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Penwest Pharmaceuticals Co. ("Penwest"), for their Complaint against defendant Impax Laboratories, Inc. ("Impax"), allege as follows.

**PARTIES**

1. Endo is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. Endo is a specialty pharmaceutical company engaged in the research, development, sale and marketing of prescription pharmaceuticals used primarily to treat and manage pain, including OPANA® ER.

2. Penwest is a Washington corporation, having its principal place of business at 39 Old Ridgebury Road, Suite 11, Danbury, Connecticut 06810-5120. Penwest is a drug development company focused primarily on the identification, development and commercialization of products for diseases of the nervous system using its expertise in drug development and drug delivery technology, including the extended-release technology used in OPANA® ER.

3. Upon information and belief, Impax is a Delaware corporation, having its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

4. Upon information and belief, Impax is manufacturing generic drug products for sale and use throughout the United States, including in this judicial district.

## NATURE OF ACTION

5. This is an action for infringement of United States Patent Nos. 5,662,933 ("the '933 patent") and 5,958,456 ("the '456 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.*

## JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c) and 1400(b).

## FACTUAL BACKGROUND

7. On September 2, 1997, the U.S. Patent and Trademark Office ("PTO") duly and legally issued the '933 patent, entitled "Controlled Release Formulation (Albuterol)" to Edward Mendell Co, Inc., as assignee. Edward Mendell Co., Inc. was renamed Penwest Pharmaceuticals Co. on October 20, 1997. A true and correct copy of the '933 patent is attached as Exhibit A.

8. On September 28, 1999, the PTO duly and legally issued the '456 patent, entitled "Controlled Release Formulation (Albuterol)" to Edward Mendell Co, Inc., as assignee. A true and correct copy of the '456 patent is attached as Exhibit B.

9. Penwest is the assignee and owner of the '933 and '456 patents, and Endo is an exclusive licensee of these patents in the relevant field of use pursuant to a strategic alliance agreement with Penwest.

10. On June 22, 2006, the United States Food and Drug Administration (the "FDA") approved Endo's new drug application No. 21-610 for OPANA® ER tablets, which

contain oxymorphone hydrochloride, under § 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b), for the relief of moderate-to-severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time.

11. On October 19, 2007, Endo submitted information regarding the '933 and '456 patents to the FDA for listing in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations* (referred to as the "Orange Book"), with respect to OPANA® ER tablets. The FDA thereafter listed the '933 and '456 patents in the Orange Book with respect to OPANA® ER tablets, pursuant to 21 C.F.R. § 314.53(e).

12. Upon information and belief, prior to October 2007, Impax submitted to the FDA paperwork purporting to constitute an Abbreviated New Drug Application ("ANDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of oxymorphone hydrochloride extended-release tablets, as generic versions of OPANA® ER tablets.

13. Upon information and belief, although the FDA initially accepted Impax's ANDA for substantive review, it thereafter rescinded that acceptance.

14. Upon information and belief, Impax subsequently amended its ANDA.

15. Upon information and belief, by letter dated December 12, 2007, the FDA advised Impax that its ANDA 79-087 "has been deemed acceptable for filing and substantive review by FDA as of November 23, 2007." The FDA's letter also requested that IMPAX provide the notice and information required by 21 U.S.C. §§ 355(j)(2)(B)(i).

16. On December 13, 2007, Impax sent Penwest and Endo a notice stating that it had submitted ANDA No. 79-087 seeking approval to manufacture, use, or sell generic

oxymorphone hydrochloride extended-release tablets prior to the expiration of the '933 and '456 patents (the "Impax Notice").

17. The Impax Notice advised Penwest and Endo that Impax's ANDA included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") that, in Impax's opinion, the proposed manufacture, importation, use or sale of the generic oxymorphone hydrochloride extended-release tablets described in its ANDA would not infringe any claim of the '933 or '456 patents.

18. In the Impax Notice, Impax did not assert that either patent is invalid.

**COUNT I**

**INFRINGEMENT OF THE '456 PATENT**

19. Plaintiffs incorporate each of the preceding paragraphs 1 to 18 as if fully set forth herein.

20. Impax's submission of an amended ANDA to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '456 patent under 35 U.S.C. § 271(e)(2)(A).

21. Impax's commercial manufacture, offer for sale or sale of its proposed generic oxymorphone hydrochloride extended-release tablets would infringe the '456 patent.

22. Upon information and belief, Impax was aware of the existence of the '456 patent as demonstrated by its reference to that patent in its ANDA, and was aware that the filing of its Paragraph IV Certification with respect to the '456 patent constitutes infringement of that patent. This is an exceptional case.

## COUNT II

## INFRINGEMENT OF THE '933 PATENT

23. Plaintiffs incorporate each of the preceding paragraphs 1 to 22 as if fully set forth herein.

24. Impax's submission of an amended ANDA to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '933 patent under 35 U.S.C. § 271(e)(2)(A).

25. Impax's commercial manufacture, offer for sale or sale of its proposed generic oxymorphone hydrochloride extended-release tablets would infringe the '933 patent.

26. Upon information and belief, Impax was aware of the existence of the '933 patent as demonstrated by its reference to that patent in its ANDA, and was aware that the filing of its Paragraph IV Certification with respect to the '933 patent constitutes infringement of that patent. This is an exceptional case.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Impax has infringed the '456 patent;

B. A judgment that Impax has infringed the '933 patent;

C. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Impax's ANDA No.79-087 under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the expiration date of the '456 and '933 patents, including any extensions;

D. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Impax, its officers, agents, servants and employees, and those persons in active

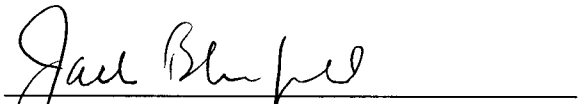
concert or participation with any of them, from infringement of the '456 and '933 patents for the full terms thereof, including any extensions; and

E. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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